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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/878,641	06/11/2001	Cato T. Laurencin	DRE-0055	2890
26259	7590	03/16/2005		
LICATLA & TYRRELL P.C. 66 E. MAIN STREET MARLTON, NJ 08053			EXAMINER CHATTOPADHYAY, URMI	
			ART UNIT 3738	PAPER NUMBER
DATE MAILED: 03/16/2005				

Please find below and/or attached an Office communication concerning this application or proceeding.

8N

Office Action Summary	Application No. 09/878,641	Applicant(s) LAURENCIN ET AL.	
	Examiner Urmi Chattopadhyay	Art Unit 3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 January 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-11 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment

1. The amendment filed 1/5/05 has been entered. Claims 1-11 remain pending and are being considered for further examination on the merits.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 1-3 and 6-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wolowacz et al. (WO 95/01810 A1, as cited in applicant's IDS) in view of Chervitz (USPN 4,917,699 as cited in previous office action).

Wolowacz et al. discloses a replacement construct for tendons or ligaments with all the elements of claims 1 and 2, but is silent to the braided scaffold being a three-dimensional braided scaffold formed using a three-dimensional textile braiding technique. The ligament replacement (page 1, lines 3-5) includes a braided polymeric fiber-based (page 16, lines 32-35), degradable scaffold (page 2, lines 5-11). The scaffold is seeded with cells (page 1, lines 27-30) using a method that implies that the scaffold is porous (page 17, lines 19-21). See page 8, lines 20-21 for the ingrowth of the cells being supported by the scaffold. Chervitz teaches a prosthetic ligament comprising a three-dimensional braided scaffold formed using a three-dimensional

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textile braiding technique in order for an individual strand of fiber to extend in all directions within the prosthetic ligament to generate strength and elasticity akin to that for natural ligaments. The three-dimensional braiding also provides the optimal orientation for a plurality of fibers to substantially replicate the behavior of natural ligament and the increased fiber redundancy to reduce cracks. See column 2, lines 43-49 and column 3, lines 1-27. It would have been obvious to one of ordinary skill in the art at the time of applicant's invention to look to the teachings of Chervitz to modify the standard braided scaffold of Wolowacz et al. to a three-dimensional braided scaffold formed using a three-dimensional textile braiding technique in order for the prosthetic ligament to generate strength and elasticity akin to that for natural ligaments. The three-dimensional braiding also provides the optimal orientation for a plurality of fibers to substantially replicate the behavior of natural ligament and the increased fiber redundancy to reduce cracks. See column 1, lines 26-32 and 43-50.

Claim 3, see page 2, lines 1-3 for the cells being fibroblasts, which are mesenchymal in origin.

Claims 6 and 7, see page 1, lines 3-5 and page 5, lines 4-16 for a method of replacing a damaged ligament.

Claim 8, see pages 16-17, steps (a)-(c) of Example 1 for a method of producing a graft material composed of living cells in a degradable matrix comprising harvesting and culturing cells in a culture and seeding the cultured cells onto the scaffold of claim 1 by sucking cell suspension through the scaffold under vacuum.

Claim 9, see page 16, lines 18-20 for the cells being fibroblasts, which are mesenchymal in origin.

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4. Claims 4, 5, 10 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wolowacz et al. in view of Chervitz as applied to claims 2 and 8 above, and further in view of Vacanti (USPN 5,855,610 as cited in previous office action).

Wolowacz et al., as modified by Chervitz, discloses a replacement construct for tendons or ligaments and a method of producing a graft material with all the elements of claims 2 and 8, including the cells being precursor cells to fibroblasts (page 2, lines 1-3), but is silent to the cells generating mesenchymal cells, as required by claims 4 and 10, and of the cells being pluripotent stem cells, as required by claims 5 and 11. Vacanti et al. teaches a replacement construct comprising a degradable, polymeric fiber-based, porous scaffold seeded with cells, wherein the cells are pluripotent stem cells because they are immunologically inert. See column 6, lines 50-53. It would have been obvious to one of ordinary skill in the art to modify the replacement construct of Wolowacz et al. by seeding the scaffold with pluripotent stem cells, which are cells that generate mesenchymal cells, because they are immunologically inert.

Response to Arguments

5. Applicant's arguments filed 1/5/05 have been fully considered but they are not persuasive. Applicant argues that the teachings of Chervitz are in no way predictive of successfully producing a three-dimensional braided scaffold of degradable polymeric fibers because Chervitz utilizes different fibers with different mechanical properties to those claimed in the instant claimed invention. Therefore, applicant asserts that the combination of references fails to meet all the criteria to establish prima facie case of obviousness with respect to the instant claimed invention. The examiner disagrees for the following reasons:

MPEP 2143: Basic Requirements of a Prima Facie Case of Obviousness

To establish a prima facie case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, not in applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991).

6. The examiner contends that all three basic criteria have been met. First, the motivation to combine Chervitz to Wolowacz et al. is found in the Chervitz reference itself, and that motivation is for the prosthetic ligament to generate strength and elasticity akin to that for natural ligaments, and have the optimal orientation for a plurality of fibers to substantially replicate the behavior of natural ligament and the increased fiber redundancy to reduce cracks. Second, there is a reasonable expectation of success because Chervitz neither explicitly teaches that the three-dimensional braiding technique can only be used with UHMWPE fibers nor explicitly teaches against using the three-dimensional braiding technique with degradable polymeric fibers. Third, the combined references do teach all the claim limitations, wherein Wolowacz et al. teaches the ligament replacement including a braided, polymeric fiber-based, porous degradable scaffold seeded with cells and Chervitz teaches a prosthetic ligament comprising a three-dimensional braided scaffold formed using a three-dimensional textile braiding technique.

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2143.02 Reasonable Expectation of Success Is Required

OBVIOUSNESS REQUIRES ONLY A REASONABLE EXPECTATION OF SUCCESS

The prior art can be modified or combined to reject claims as prima facie obvious as long as there is a reasonable expectation of success. In re Merck & Co., Inc., 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

7. As explained above, there is a reasonable expectation of success. Chervitz teaches a non-degradable polymeric three-dimensional braided replacement ligament construct formed using a three-dimensional textile braiding technique in order for an individual strand of fiber to extend in all directions within the prosthetic ligament to generate strength and elasticity akin to that for natural ligaments and to provide the optimal orientation for a plurality of fibers to substantially replicate the behavior of natural ligament and the increased fiber redundancy to reduce cracks. When the three-dimensional braiding technique of Chervitz is applied to the degradable polymeric fibers of Wolowacz et al., there is a reasonable expectation of success that the three-dimensional braid created will have an individual strand of fiber extending in all directions within the prosthetic ligament to generate strength and elasticity akin to that for natural ligaments and will have the optimal orientation for a plurality of fibers to substantially replicate the behavior of natural ligament and the increased fiber redundancy to reduce cracks.

**AT LEAST SOME DEGREE OF PREDICTABILITY IS REQUIRED;
APPLICANTS MAY PRESENT EVIDENCE SHOWING THERE WAS NO
REASONABLE EXPECTATION OF SUCCESS**

Obviousness does not require absolute predictability, however, at least some degree of predictability is required. Evidence showing there was no reasonable expectation of

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success may support a conclusion of nonobviousness. In re Rinehart, 531 F.2d 1048, 189 USPQ 143 (CCPA 1976).

8. Applicant has not provided any evidence showing that there was no reasonable expectation of success. Merely arguing that prior to the present invention, three-dimensional braiding of degradable polymers had not been successfully performed due to the nature of the mechanical forces involved and the differences in the mechanical properties of degradable fibers versus fibers such as taught by Chervitz is not sufficient.

Conclusion

9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

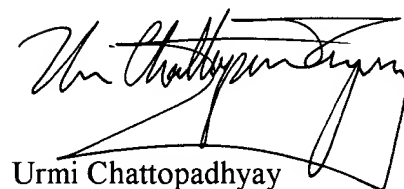
A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Urmi Chattopadhyay whose telephone number is (571) 272-4748. The examiner can normally be reached on Tuesday-Thursday 10:00am - 6:00pm.

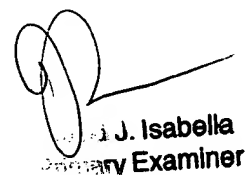
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571) 272-4754. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Urmi Chattopadhyay

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J. Isabella
Examiner